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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,502

02/05/2004

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EXAMINER

EPPS FORD, JANET L

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/772,502	<b>Applicant(s)</b> ROZEMA ET AL.	
	<b>Examiner</b> Janet L. Epps-Ford	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16, 19, 20, 22-27, 30, 33, 34, 36, 37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 19, 20, 22-27, 30, 33, 34, 36, 37 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 13-16, 19-20, and 22-27, 30, 33-34, 36-37, 39 are pending for examination.

### ***Claim Objections***

4. The objection to claim 13 set forth in the prior Office Action is withdrawn in response to Applicant's amendment filed 3/07/08.

### ***Double Patenting***

5. The rejection of claims 13, 16-17 and 22-24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13, and 18-21 of U.S. Patent No. 7,098,032 (of record 12/18/06), is withdrawn.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 13-16, 19-20, and 22-27, 30, 33-34, 36-37, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Trubetskoy et al (US 7,098,032)

9. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

10. US Patent 7,098,032 teaches amphiphilic polymers (column 20, lines 64- column 21) and “Membrane Active” compounds (column 21, 12-31). Additionally, claims 11-13, 18-21 deal with the making an amphipathic copolymer comprising a polycation and a polyanions. Example 2 of Patent 7,098,032 uses polyvinyl ether to produce polycations, which are used in the amphiphilic copolymers of patented claim 11. Additionally,

examples 5-6 of Patent 7,098,032 teach the formation of pH-labile polyampholytes using CDM thioesters and cysteine-modified polycations, and the formation of polymer and DNA complexes in the presence of CDM modified polymers in the presence of HEPES, which are the same steps of preparation that produces the amphiphilic polymers of the instant specification (see page 17 line 22 through page 18 line 27; and page 20).

11. In one particular embodiment Trubetskoy et al. describes the synthesis of Poly(Alkyl enoether-co-vinyloxy Ethylamine) Polymers, see col. 40. Furthermore, Trubetskoy et al. teach that polyampholytes of their invention, which includes polyvinylether copolymers, wherein the copolymers can include alternating, random, block and graft. Trubetskoy et al. also teach that these polyampholytes can comprise membrane active compounds, wherein the compounds are capable of lysing red blood cells, see example 9.

12. In another embodiment of Trubetskoy et al. describes the synthesis of polyanions, for example Polyvinyl(2-methyl-4-hydroxymethyl(succinic anhydride ester)-1,3-dioxolane, see example 3.

Furthermore, Trubetskoy et al. teach the following:

13. “[P]lacement of both reactive groups (amide and carboxylic acid) in the same molecule accelerates their reaction such that amine-anhydride reactivity becomes functionally reversible. For example, the amide-acid product of succinic anhydride and a primary amine cleaves back to amine and anhydride 10,000 times faster than the products between noncyclic anhydride and a primary amine. In particular, the product

of primary amines with maleic anhydride and maleic anhydride derivatives, maleamic acids, revert back to amine and anhydride with amazing speed...” This portion of Trubetskoy et al., in combination with other portions of this reference reads on the limitations of claim 19, and those dependent therefrom.

***Claim Rejections - 35 USC § 102***

14. The rejection of Claims 13-17, 19-20, 22 and 25-30 and claims 31-40, under 35 U.S.C. 102(e) as being anticipated by Meier et al (US Patent No: 6,616,946) of record 12/18/06; and the rejection of claim 23-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Meier et al (US Patent No: 6,616,946) in view of Merdan et al (Prospects for cationic polymers in gene and oligonucleotide therapy against cancer, Advanced Drug Delivery Reviews, 2002. 54:715-758) of record 12/18/06, is withdrawn in response to Applicant's amendment.

***Claim Rejections - 35 USC § 102***

15. Claims 13-16, 19-20, and 22-27, 30, 33-34, 36-37, and 39 remain rejected under 35 U.S.C. 102(e) or (a) as being anticipated by Trubetskoy et al. (US 2003/0026841 A1), for the reasons of record.

16. Applicant's reply filed 9/10/08 was incomplete since it did not include a reply to this rejection.

17. The instant claims remain rejected for the reasons of record, set forth below:

18. US Patent Application 20030026841 teaches a process for delivery of a polyion to a cell, comprising: forming a complex of labile polyampholyte and polyion; and, delivering the complex into a cell (¶ [0022]).

The complexes of the invention are disclosed as useful for both gene therapy, which includes both delivery of gene that expresses a foreign or native protein, or antisense or ribozymes to inhibit the expression of an mRNA ([0016]-[0019]).

In regards to polyampholytes of this invention, it is stated that:

[0059] **Random copolyampholytes** are polyampholytes in which the cationic and anionic monomers repeat in a random fashion. The monomers in these polyampholytes may, but need not be, polymers themselves. Cleavage of the bonds between monomers results in anions and cations or polyanions and polycations (if the monomers are polyanions and polycations).

Additionally, in regards to the polymers of this invention, it is stated that:

[0151] A polymer is a molecule built up by repetitive bonding together of smaller units called monomers. In this application the term polymer includes both oligomers which have two to about 80 monomers and polymers having more than 80 monomers. The polymer can be linear, branched network, star, comb, or ladder types of polymer. The polymer can be a homopolymer in which a single monomer is used or can be copolymer in which two or more monomers are used. **Types of copolymers include alternating, random, block and graft.**

Moreover, this reference teaches amphiphilic polymers (¶ [0140]) and "Membrane Active" compounds (see ¶ [0142]). Example 2 uses polyvinyl ether to produce polycations, which are used in the amphiphilic copolymers of patented claim 11.

Additionally, examples 5-6 (pages 25-28) teach the formation of pH-labile polyampholytes using CDM thioesters and cysteine-modified polycations, and the formation of polymer and DNA complexes in the presence of CDM modified polymers in the presence of HEPES, which are the same steps of preparation that produces the

amphiphilic polymers of the instant specification (see page 17 line 22 through page 18 line 27; and page 20).

Thus the polyvinylether polymers produced in this reference are inherently amphiphilic, in addition to being polyampholytes, moreover random copolymers are also encompassed by this reference.



19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633

/JLE/